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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/670,568	09/27/00	IKAWA Y	061014

EXAMINER	
DAVIS N	
ART UNIT	**PAPER NUMBER**
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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/670,568	Applicant(s) IKAWA ET AL.	
	Examiner Natalie A. Davis	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 July 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8 and 15-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8 and 15-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant's election without traverse of Group I, claims 1-8 and 15-18 in Paper No. 12 is acknowledged.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-8 and 15-18 are being examined as belonging to the elected Group I, while claims 9-14 are withdrawn from examination as being drawn to a non-elected invention.

Information Disclosure Statement

The information disclosure statement filed 27 September 2000 has been considered. A signed copy is attached hereto.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15-16 are rejected under 35 U.S.C. 112, second paragraph, as being dependent upon a nonelected base claim and must be rewritten in independent form including all of the limitations of the base claim and any intervening claims.

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-2, 4-8 and 15-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a gene encoding a protein having an amino acid sequence shown under SEQ ID NO. 1 and transcriptional, cell growth inhibiting, and apoptosis inducing

activities as p51 activity, does not reasonably provide enablement for a gene encoding a protein having an amino acid sequence derived from SEQ ID NO: 1 by deletion, substitution, or addition of one or a plurality of amino acids having p51 activity and any activities other than those mentioned supra as p51 activities. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir., 1988). They include: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The claims are drawn to a gene coding for a protein which has an amino acid sequence derived from SEQ ID NO: 1 by deletion, substitution, or addition of one or a plurality of amino acids having p51 activity.

4. The specification discloses that the invention comprises a gene "encoding a protein having an amino acid sequence derived from SEQ ID NO: 1 by deletion, substitution, or addition of one ~ a few or a plurality of amino acids on condition that the above mentioned qualifications are satisfied." It further discloses that the extent of deletion, substitution or addition of amino acids and the site or sites involved are not particularly restricted inasmuch a the protein so modified is functionally equivalent to the protein of SEQ ID NO:1 (page 27-28). The specification defines p51 activity as transcriptional, cell growth inhibiting, and apoptosis inducing (page 22). It further defines p51 activity as applied to the to the known activities and functional features of the p53 protein and states that the p51 protein has some or all of these actions and functions (page 28-29). Furthermore, the disclosure exemplifies apoptosis induction by p51 cDNA induction (page 123-127), but does not provide any guidance or exemplification of biological activity beyond transcriptional control, cell growth inhibition, and apoptosis induction. One cannot extrapolate the teachings of the specification to the scope of the claims because the claims are broadly drawn to any gene encoding any protein with an amino acid sequence derived from SEQ ID NO: 1 by deletion, substitution, or addition of one or a plurality of amino acids

having p51 activity, and applicant has not enabled all of these types of derivations because it has not been shown that these derivations are capable of functioning as that which is being disclosed. In addition, the specification does not give any guidance to which derivation will exhibit the biological activities as the claimed gene, or any guidance as to which regions of amino acid sequence are responsible for biological activity and thus, must be preserved so the molecule will function as claimed. Applicant has not enabled all types of derived proteins, which are capable of functioning as that which is disclosed. Furthermore, it would require the experimentation of numerous derived amino acids to assay for gene encoding a protein having an amino acid sequence derived from SEQ ID NO: 1 by deletion, substitution, or addition and functions as contemplated. Therefore, in view of the lack of predictability of the prior art and the absence of working examples showing p51 activity beyond transcriptional control, cell growth inhibition, and apoptosis induction, it would require undue experimentation for one of skill in the art to practice the invention as claimed.

5. Claims 1-2 are rejected less than 35 U.S.C. 112, first paragraph. The instant specification does not contain a written description of the invention in such full, clear, concise, and exact terms or in sufficient detail that one skilled in the art can reasonably conclude that applicant had possession of the claimed invention at the time of filing.
Vas-Cath Inc. v. Mahurkar (CA FC) 19 USPQ2d 1111 (6/7/1991) clearly states that "written description" of invention required by first paragraph of 35 U.S.C. 112 is separate and distinct from that paragraph's requirement of enabling disclosure, since description must do more than merely provide explanation of how to "make and use" invention; applicant must also convey, with reasonable clarity to those skilled in art, that applicant, as of filing date sought, was in possession of invention, with invention being, for purposes of "written description" inquiry, whatever is presently claimed. An applicant shows possession by describing the claimed invention with all it limitations using such descriptive means as words, structures, diagrams, and formulas. Also, description of an actual reduction to practice, or by showing the invention was "ready for patenting," or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention at the time of filing.

The claims are drawn to a gene coding for a protein which may have: a) an amino acid sequence shown under SEQ ID NO: 1 or b) an amino acid sequence derived from SEQ ID NO: 1 by deletion, substitution, or addition of one or a plurality of amino acids having p51 activity. The claims are further drawn to a gene or cDNA comprising the following DNA: a) DNA identified by nucleotides 145-1488 of SEQ ID NO: 2 or b) DNA capable of hybridizing to nucleotides 145-1488 of SEQ ID NO: 2.

6. The specification defines a gene as DNA, which is not only double stranded but also single stranded, inclusive of sense and antisense strands. A gene may include cDNA, single stranded DNA, which is complementary to sense and antisense strands, and all fragments thereof (page 19). The disclosure indicates the gene was acquired via PCR using primers that were derived from specific regions of the p53 and p73 genes, the gene fragment is similar to these genes, and was used as a probe to isolate a cDNA clone. However, the disclosure does not give sufficient descriptive information, such as definitive structural features, location of introns, exons, and open reading frames, chromosomal localization, or complete detailed description of the function of claimed invention indicating that the claimed gene was indeed isolated, produced, and assayed for the uses disclosed. Thus, one skilled in the art would not recognize from the disclosure that the applicant was in possession of the claimed gene.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

7. Claims 1-2, 4-8, and 15-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Yang, et al., (1998). The claims are drawn to a gene coding for a protein which may have: a) an amino acid sequence shown under SEQ ID NO: 1 or b) an amino acid sequence derived from

SEQ ID NO: 1 by deletion, substitution, or addition of one or a plurality of amino acids having p51 activity. The claims are further drawn to a gene or cDNA comprising the following DNA: a) DNA identified by nucleotides 145-1488 of SEQ ID NO: 2 or b) DNA capable of hybridizing to nucleotides 145-1488 of SEQ ID NO: 2. The claims are further drawn to DNA, which is capable of hybridizing to nucleotides 145-1488 of SEQ ID NO: 2 under stringent conditions, the DNA may further be used as a probe or primer. The claims further comprise a vector harboring the gene of claim 1, host cell, and a method of making the protein comprising growing the host cell.

Yang, et al. teach the amino acid of SEQ ID NO: 1, which is called p63. Yang, et al, describe the cloning of p63, a gene that has a strong homology to p53 and p73. Since the amino acid sequence is identical to that which is claimed, it is inherent that it is the same gene (p51) and possesses the same biological activities as the claimed invention. Furthermore, Yang, et al. teach PCR primers and probes used to amplify the p63 gene, which bind under stringent conditions. It is inherent that the probes and primers will hybridize to nucleotides 145-1488 of SEQ ID NO: 2, since SEQ ID NO: 2 encodes part of the p63 (p51) gene. Thus, the prior art reference teaches the invention as claimed.

8. Claims 1-2, 4-8, and 15-18 are rejected under 35 U.S.C. 102(e) as being anticipated by McKeon, et al., (WO 99/19357). The claims are drawn to a gene coding for a protein which may have: a) an amino acid sequence shown under SEQ ID NO: 1 or b) an amino acid sequence derived from SEQ ID NO: 1 by deletion, substitution, or addition of one or a plurality of amino acids having p51 activity. The claims are further drawn to a gene or cDNA comprising the following DNA: a) DNA identified by nucleotides 145-1488 of SEQ ID NO: 2 or b) DNA capable of hybridizing to nucleotides 145-1488 of SEQ ID NO: 2. The claims are further drawn to DNA, which is capable of hybridizing to nucleotides 145-1488 of SEQ ID NO: 2 under stringent conditions, the DNA may further be used as a probe or primer. The claims are further drawn to a gene comprising a nucleotide sequence coding for the polypeptide defined in claims 12 or 13, which comprise amino acids 1-59 or 142-321 of SEQ ID NO: 1. The claims further comprise a vector harboring the gene of claim 1, host cell, and a method of making the protein comprising growing the host cell.

McKeon, et al. teach the amino acid of SEQ ID NO: 1, which is called p63. McKeon, et al, describe the cloning of p63, a gene that has a strong homology to p53 and p73. Since the amino acid sequence is identical to that which is claimed, it is inherent that it is the same gene (p51) and possesses the same biological activities as the claimed invention. McKeon, et al. further teach a gene comprising by nucleotides 145-1488 of SEQ ID NO: 2, DNA, which binds under stringent conditions to SEQ ID NO: 2, as PCR primers were used to probe and amplify the p63 gene. Thus, the prior art reference teaches the invention as claimed.

9. Claim 2 is rejected under 35 U.S.C. 102(b) as being anticipated by Osada, et al., (1998). The claim is drawn to a gene, which has the nucleotide sequence of SEQ ID NO: 2.

Osada, et al., teach the human p 51 gene, which comprises SEQ ID NO: 2, thus teaching the invention as claimed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie A. Davis whose telephone number is 703-308-6410. The examiner can normally be reached on M-F 8-5:30 (every other Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4315 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Natalie A. Davis, Ph.D.
September 5, 2001

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